IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP.
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION MDL No. 2326

THIS DOCUMENT RELATES TO THE CASES ON THE ATTACHED EXHIBIT A

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Dr. Nathan L. Guerette)

Pending in *In re Boston Scientific Corp.*, No. 2:12-md-2326, MDL 2326, is the Plaintiffs' Motion to Exclude Certain Opinions and Testimony of Dr. Nathan L. Guerette. [ECF No. 4823]. The Motion is now ripe for consideration because the briefing is complete. As set forth below, the plaintiffs' Motion is **DENIED in part** and **RESERVED in part**.

I. Background

This group of cases resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation ("MDL") concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the six remaining MDLs, there are more than 17,000 cases currently pending, approximately 3800 of which are in the Boston Scientific Corp. ("BSC") MDL, MDL No. 2326.

In an effort to manage the massive BSC MDL efficiently and effectively, I decided to conduct pretrial discovery and motions practice on an individualized basis.

To this end, I selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, I enter a docket control order subjecting each active case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order ("PTO") # 165, *In re Bos. Sci. Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-02326, June 21, 2017, http://www.wvsd.uscourts.gov/MDL/boston/orders.html. Included among the discovery rules imposed by the court is the obligation of the parties to file *Daubert* motions seeking to limit or exclude the testimony of general causation experts in the main MDL, MDL 2326.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods," which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. However, he or she must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court's role as gatekeeper is an important one. "[E]xpert witnesses have the potential to be both powerful and quite misleading"; the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I "need not determine that the proffered expert testimony is irrefutable or certainly correct. As with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (citation omitted) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 ("All *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful.").

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'" (alteration in original)); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

III. Analysis

Dr. Guerette is a practicing urogynecologist who is board-certified in the fields of Female Pelvic Medicine and Reconstructive Surgery, and Obstetrics and Gynecology. He is the Director and President of the Female Pelvic Medicine Institute of Virginia, and is a clinical professor at Virginia Commonwealth University. He performs an average of approximately 500 to 600 pelvic floor surgeries each year.

A. Safety and Efficacy

First, plaintiffs argue that Dr. Guerette's opinions on the safety and efficacy of the Solyx sling are unreliable because he failed to consider "an abundance of relevant and applicable medical literature." To the extent that plaintiffs believe that Dr. Guerette failed to consider relevant medical literature that is contrary to his opinions, such matters go to the weight of his opinions, not its admissibility. The plaintiffs' Motion on this point is **DENIED**.

B. Adequacy of Warnings

Second, plaintiffs argue that Dr. Guerette is unqualified to opine on the adequacy of the Solyx Directions for Use ("DFU") because he has no specific expertise in the area of product warnings. I have repeatedly ruled that, without additional expertise in the specific area of product warnings, a doctor is not qualified to opine that a product warning is adequate merely because it includes risks that he observed in his own practice. In response, BSC argues that Dr. Guerette has additional qualifications, beyond his clinical experience, that render him qualified to opine on product warnings. Specifically, BSC states that "Dr. Guerette has worked on DFUs under a consulting agreement with another company." BSC's Mem. in Opp'n to Pls.' Mot. to Exclude Certain Ops. & Testimony of Dr. Nathan Guerette 6 [ECF No. 4977]. BSC provides no further details on Dr. Guerette's "additional qualifications" in the area of product warnings. Therefore, I **FIND** that I do not have sufficient information at this time to determine whether Dr. Guerette is qualified to opine on the adequacy

of the Solyx DFU. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

C. Physical Properties of Mesh

Third, plaintiffs argue that Dr. Guerette's opinions on the physical properties of the Solyx are unreliable, and that he is unqualified to offer such opinions. Dr. Guerette is an experienced urogynecologist, and he has performed many surgeries implanting and removing polypropylene mesh devices used for the treatment of SUI. I have generally found that such experience qualifies physicians to opine on the properties of polypropylene irrespective of a lack of specialized knowledge of biomaterials. I likewise find that Dr. Guerette's experience with polypropylene mesh devices sufficiently qualifies him to offer opinions regarding foreign body reaction, shrinkage, and degradation. The plaintiffs' Motion as to this point is **DENIED**.

Plaintiffs challenge the reliability of Dr. Guerette's opinion on the physical properties of mesh—specifically that the device in question does not degrade, shrink, or cause a foreign body reaction. Dr. Guerette claims he based this opinion on his clinical experience, during which he did not observe evidence of such mesh properties, and upon relevant medical and scientific literature.

The advisory committee notes to Rule 702 state:

> If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply "taking the expert's word for it."

Fed. R. Evid. 702 advisory committee's note to 2000 amendment (citing *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) ("We've been presented with only the expert's qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough.")).

Yet the Fourth Circuit appears more willing to "take the expert's word for it" so long as the expert has demonstrated that he or she has experience in a field writ large. *See, e.g.*, *Eskridge v. Pac. Cycle, Inc.*, 556 F. App'x 182, 190–91 (4th Cir. 2014) (unpublished) (finding a bicycle engineer's experience with "hundreds of cases of accidents" and "decades of experience in the industry in general" provided a reliable basis to testify about whether bicycle purchasers read warnings and dismissing concerns that the bicycle expert's testimony was nothing more than personal opinion because of his "years of experience" and assurance that all of his opinions were "to a reasonable degree of engineering certainty").

On the one hand, Dr. Guerette has based his opinions on his extensive clinical experience and a review of the medical and scientific literature; in the abstract, these are reasonable bases from which to form an expert opinion. *See Kumho*, 526 U.S. at 156 ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.").

On the other hand, the court does not have enough information to judge the reliability or relevance of these particular clinical observations—as distinguished from experience examining mesh explants. Perhaps Dr. Guerette did not observe evidence of mesh degradation and shrinkage because he was not looking. Or perhaps

his method of identifying and tracking the complications at issue is not scientifically sound. Additionally, sweeping statements about support within the medical community or medical literature can be difficult to assess. Although the expert report indicates Dr. Guerette reviewed an extensive list of literature in forming his opinions generally, the court is directed to minimal specific support for the statements at issue or detail about Dr. Guerette's methodology.

In this specific context, I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony on physical mesh properties based primarily on a doctor's clinical observations, or lack thereof. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

D. Material Safety Data Sheet ("MSDS")

Finally, plaintiffs object to Dr. Guerette's opinions regarding the MSDS provided by Chevron Phillips—specifically, that Dr. Guerette has never consulted an MSDS, that he is unaware of any scientific basis for the MSDS's express prohibition of use of the material in the human body, and that doctors generally do not review or rely on the MSDS in their practices. Dr. Guerette's opinions on his and other doctors' experience with the MSDS for raw polypropylene pellets is not relevant or helpful to the jury. The pertinent issue is not whether doctors rely on or heed MSDS warnings for the raw materials BSC uses to manufacture its medical devices. *See Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 577 (S.D. W. Va. 2014) (excluding a doctor's opinions on the MSDS because "[a] narrative review of the history and development of MSDSs

and who uses them in the field is not helpful to the jury"). Nevertheless, I acknowledge the need for rebuttal testimony based on what the plaintiffs present at trial. Accordingly, I **RESERVE** ruling on the admissibility of Dr. Guerette's MSDS opinions for trial.

IV. Conclusion

To summarize, the plaintiffs' *Daubert* Motion concerning Dr. Guerette [ECF No. 4823] is **DENIED in part** and **RESERVED in part**.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2326 and all individual cases listed on the attached Exhibit A. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: May 29, 2018

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

EXHIBIT A

Case Number	Case Name
2:17-cv-02589	Barnett v. Boston Scientific Corporation
2:17-cv-02599	Reyes v. Boston Scientific Corporation
2:17-cv-02636	Walseth v. Boston Scientific Corporation